

Albumin versus Crystalloid Therapy in the Management of Hepatorenal Syndrome: A Model for using Meta Analysis in Cost Effectiveness Studies and the Design of Clinical Trials

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ABSTRACT

We applied traditional methods of gathering, integrating and summarizing findings of current literature, with new approaches for assessing the cost effectiveness of two treatments for hepatorenal syndrome (HRS). Findings of this cost effectiveness study are used to form a proposal for a multi-center prospective clinical trial, to assess the economic and clinical benefits of albumen versus crystalloid therapy in the care of these patients. Our initial findings suggest that albumin therapy is superior to standard crystalloid therapy, in the treatment of HRS patients. The number of survival days appears to increase with this form of therapy per dollar cost, while patients await liver transplantation.

STUDY OBJECTIVES

- 1) Complete a literature search, summarizing clinical and economic implications of treating HRS patients, as well as probabilities of outcomes of treatment, where known.
- 2) Describe pre-transplant treatment of HRS patients with a decision tree, identifying risk factors, clinical conditions, treatment options, and outcomes within the scope of this study, ie, Albumin versus Crystalloid treatment.
- 3) Assess the cost-effectiveness of albumin infusion with octreotide and midodrine over standard therapy in correcting functional renal insufficiency in cirrhotic patients with type 1 or type 2 HRS.

METHODS

A systematic review of the literature yielded several publications with valid measures of survival and costs of treatment, associated with similar treatments for HRS. Figures were statistically combined, adjusting for differing intervals of survival and other differences between their study methods. Survival probabilities and costs were populated into decision analysis trees, using DATA Pro software by TreeAge Software, Inc. Sensitivity analyses were performed to test underlying assumptions. For example, patients choosing Albumin therapy were expected to survive two weeks, with a probability of .30.

A range of probabilities +/- .30 were tested in a sensitivity analysis, with regard to cost/effectiveness outcomes.

FINDINGS & DISCUSSION

Values in the decision tree were "rolled back" to evaluate an optimal path at the decision node of albumin therapy vs. standard therapy. Albumin therapy was shown to support 19.5 days survival at a cost of \$26,711. This form of therapy is optimal, in contrast to standard therapy which yielded an expected 10.9 days of survival at a cost of \$22,086.

The body of literature addressing cost effectiveness of alternative medical treatments is expanding exponentially, with increasing economic scrutiny by payers and providers, and a concomitant refinement of research methods in economics and information science. The cost/effectiveness of treating liver disease in the U.S. has gained significant attention among health care providers and payers during the past few decades. While transplantation of patients with end-stage disease has become more successful, the higher costs associated with these treatments are increasingly weighed against use of limited funds to serve a greater number of patients with less intense needs. These deliberations address fundamental economic principals which in a managed health care environment, translate directly into decisions about specific medical and surgical treatments. Physicians are expected to justify practices and show the value of their services. Insurers are less willing to pay for services which haven't been empirically proven to yield effective outcomes.

Recent issues of JAMIA have articulated the need for stronger collaboration between the fields of health informatics and health services research. This paper combines methods from informatics, economics and epidemiology. Methods employed here, should also be of use to policymakers, payers and providers, who are investigating the cost effectiveness of alternative treatments, based upon existing literature or other evidence-based data sources.